

REMARKS

Claims 1, 3, 4, 8-10, 13-15, 28, 29, and 33-46 are pending in the application. Claim 41 has been amended and new claims 45 and 46 have been added. Claim 41 has been amended to clarify the invention and state a "substrate of the prosthesis". Support for new claims 45 and 46 is found on at least page 3, lines 20-24, and page 17, lines 5-11. Applicants respectfully assert that no new matter has been added and request reconsideration of the claims currently pending in the application.

Applicants thank the Examiner for favorable consideration and allowance of claims 28, 29, 33, 43, and 44.

On page 2 of the Office Action, claims 1, 8, 10, 13, 15, 34, 35, and 38-40 are provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1, 2, 9, 14, 21, and 29 of copending Application No. 09/014,087. Applicants will consider filing a Terminal Disclaimer when the claims have been found otherwise allowable.

On page 3 of the Office Action, claims 1, 3, 4, 8, and 9 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Cahalan, et al. (U.S. Patent No. 5,308,641). Applicants respectfully traverse the rejections.

On page 4 of the Office Action, claim 41 is rejected under 35 U.S.C. § 102(a) as being anticipated by Sharp, et al. (WO 98/00695). Applicants respectfully traverse the rejections.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros.*

v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. Applicants respectfully submit that Cahalan, et al. does not teach every element of claim 1, and therefore fails to anticipate claim 1. In particular, Cahalan, et al. does not teach a polypeptide growth factor associated with a substrate of a biomedical device by covalent bonding using crosslinking agents comprising at least two aldehyde functional groups that form covalent bonds to link the crosslinking agent directly with the polypeptide growth factor and the substrate, or antibody-antigen associations, or specific binding protein-receptor associations, or enzyme-substrate associations, to stimulate association of viable cells with the substrate. Rather, Cahalan, et al. teaches the use of a spacer of improved stability to which a crosslinking agent is attached, thus teaching away from Applicants' association with or direct crosslinking of a polypeptide growth factor with the substrate.

Dependent claims 3, 4, 8, and 9, which are dependent from independent claim 1, were also rejected under 35 U.S.C. §102(b) as being anticipated by Cahalan, et al. While Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claim 1. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 3, 4, 8, and 9 are also in condition for allowance.

Applicants respectfully request withdrawal of the rejection of claims 1, 3, 4, 8, and 9 under 35 U.S.C. §102 (b) as being anticipated by Cahalan, et al.

With respect to the rejection of claim 41 as being anticipated by Sharp, et al., claim 41 as amended herein clearly distinguishes over the teaching by Sharp, et al. of Tat protein bound to a test substrate and is clearly patentable over Sharp, et al., which does not teach the association of Tat protein with a substrate of a prosthesis.

Applicants respectfully request withdrawal of the rejection of claim 41 under 35 U.S.C. § 102(a) as being anticipated by Sharp, et al.

On page 3 of the Office Action, claims 10 and 15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cahalan, et al. in view of Goldstein (U.S. Patent No. 5,613,982). Applicants respectfully traverse the rejections.

On page 4 of the Office Action, claim 13 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Cahalan, et al. in view of Bayne, et al. (EP 0 476 983). Applicants respectfully traverse the rejection.

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142. Applicants respectfully traverse the rejections, since the prior art fails to disclose all the claim limitations and there would be no motivation to combine the references as proposed by the Examiner.

With respect to the rejection of claims 10 and 15 under 35 U.S.C. 103(a) as being unpatentable over Cahalan, et al. in view of Goldstein, as pointed out above, Cahalan, et al. do not teach a polypeptide growth factor associated with a substrate of a biomedical device by covalent bonding using crosslinking agents, wherein the crosslinking agents comprise at least two aldehyde functional groups that form covalent bonds to link the crosslinking agent directly with the polypeptide growth factor and the substrate, or antibody-antigen associations, or specific binding protein-receptor associations, or enzyme-substrate associations, to stimulate association of viable cells with the substrate. Goldstein does not supply the deficiency in Cahalan, et al., but merely discloses some of the tissues of claim 10 and some of the biomedical device types of claim 15. It is submitted that the combination of Goldstein with Cahalan, et al. does not render claims 10 and 15 obvious.

Applicants respectfully request withdrawal of the rejection of claims 10 and 15 under 35 U.S.C. § 103(a) as being unpatentable over Cahalan, et al. in view of Goldstein.

With respect to the rejection of claim 13 under 35 U.S.C.103(a) as being unpatentable over Cahalan, et al. in view of Bayne, et al., as pointed out above, Cahalan, et al. does not teach a polypeptide growth factor associated with a substrate of a biomedical device by covalent bonding using crosslinking agents, wherein the crosslinking agents comprise at least two aldehyde functional groups that form covalent bonds to link the crosslinking agent directly with the polypeptide growth factor and the substrate, or antibody-antigen associations, or specific binding protein-receptor associations, or enzyme-substrate associations, to stimulate association of viable cells

with the substrate. Bayne, et al. does not supply the deficiency of Cahalan, et al., and teaches the use of vascular endothelial cell growth factor II, which use is not suggested by Cahalan, et al. It is submitted that the combination of Bayne, et al. with Cahalan, et al. does not render claim 13 obvious.

Applicants respectfully request withdrawal of the rejection of claim 13 under 35 U.S.C. § 103(a) as being unpatentable over Cahalan, et al. in view of Bayne, et al

New claims 45 and 46 are clearly distinguishable over the cited references, none of which either alone or in combination teaches or suggests a polypeptide growth factor crosslinked to a substrate of a biomedical device or a prosthesis by covalent bonding using crosslinking agents comprising at least two aldehyde functional groups that form covalent bonds to link the crosslinking agent directly with the polypeptide growth factor and the substrate in order to stimulate association of viable cells with the substrate.

Applicants respectfully request favorable consideration and allowance of new claims 45 and 46.

In view of the amendments and reasons provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims.


If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' attorney of record, Hallie A. Finucane at (952) 253-4134.

Respectfully submitted,

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